

10/587899

INFORMATION DISCLOSURE STATEMENT	Application #	New Application
	Confirmation #	
	Filing Date	On even date herewith
	First Inventor	SCHWARTZ et al.
	Art Unit	
	Examiner	
	Docket #	P08977US00/bas

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

S I R :

This IDS is submitted pursuant to 37 CFR. §1.97-1.98 and includes the following:

- ☒ A **listing** of the references on PTO-1449.
- ☒ A copy of all **non-US** references which are listed on the PTO-1449 (US refs not required).
- ☒ A copy of a corresponding foreign **Search Report** which explains the relevance of the references noted therein.

Please note the following particulars concerning the filing of this IDS:

- ☒ 1. This IDS is filed at whichever is the latest of:
 - within three months of the filing date of a NATIONAL APPLICATION other than a CPA, or
 - within three months of the date of entry into the NATIONAL STAGE as set forth in 37 CFR. §1.491 in an international application, or
 - before the mailing date of a first Office Action on the merits or after filing of an RCE *(but if a first Office Action is mailed but not yet received and the date on the face of the attached foreign communication makes it evident that this IDS is submitted within three months from the mailing of the search report, then applicant is entitled to have this IDS considered under 2.B. below and such boxes should be considered as having been checked).*
- ☐ 2. This IDS is filed **after a first Office Action**, but before a Final Action, Allowance, or any other action which closes prosecution, **and**:
 - ☐ A. Is accompanied by a payment in the amount of \$180.00 required by 37 CFR. §1.17(p).

or

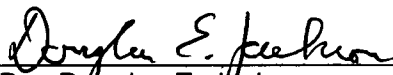
 - ☐ B. I hereby state that each item of information contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
 - ☐ C. I hereby state that no item of information in this IDS herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR. §1.56(c) more than 3 months prior to the filing of this IDS.
 - ☐ D. An appropriate Statement is attached.

10/587899

- ☐ 3. This IDS is filed **after** a final action or allowance, but on/before payment of the issue fee, and:
- ☐ A. is accompanied by a payment in the amount of \$180.00 required by 37 CFR. §1.17(p).
- and
- ☐ B. I hereby state that each item of information contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
- ☐ C. I hereby state that no item of information in this IDS herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR. §1.56(c) more than 3 months prior to the filing of this IDS.
- ☐ D. An appropriate Statement is attached.
- ☐ 4. This IDS does not comply with 37 CFR 1.97-1.98, and is being filed **for placement in the file** pursuant to 37 CFR. §1.97(i). .
- ☒ 5. It will also be appreciated that:
- a. It is believed that this IDS complies fully with 37 CFR 1.56 and 1.97-98 and with MPEP § 609; but if for some reason it does not and will not be entered, the examiner is requested to telephone the undersigned so that any deficiency can be timely remedied.
- b. Some of the documents may have markings thereon, but no significance should be attached to those markings.
- c. These documents are not necessarily analogous art.
- d. Where an English language translation of an abstract is provided from a public source, applicant cannot vouch for the accuracy of that translation.
- ☒ 6. If no payment is enclosed and a fee is due in connection with this communication or if the payment enclosed is insufficient, the Commissioner is authorized to charge any fee or additional fee due with this communication to Deposit Account No. 12-0555.

Respectfully submitted,

Date: 7/28/06


By: Douglas E. Jackson
Registration No.: 28518

STITES & HARBISON PLLC ♦ 1199 North Fairfax St. ♦ Suite 900 ♦ Alexandria, VA 22314
TEL: 703-739-4900 ♦ FAX: 703-739-9577 ♦ CUSTOMER NO. 00881

Customized PTO/SB/08a+b (07-05)

Substitute for Form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application #	New Application #
	Confirmation #	
	Filing Date	On even date herewith
	First Inventor	SCHWARTZ et al.
	Art Unit	1614
	Examiner	Spivack
Sheet 1 of 1	Docket #	P08977US00/bas

FOREIGN PATENT DOCUMENTS

Exam. Initial*	Country-Number-Kind	Publ. Date MM-DD-YYYY	Name Patentee or Applicant	Relevance Passages/Figs.	Trans- lation

NON PATENT LITERATURE DOCUMENTS

Exam. Initial*	Include NAME of the author (in CAPS), Title of Article/Item, Date, Page(s), Volume-Issue No., Publisher, City and/or Country where published	Trans- lation
/P.S./	LECOMTE JM: "An overview of clinical studies with raccadiotril in adults", Int'l Journal of Antimicrobial Agents, vol 14, no. 1 2/2000 – pages 781-87.	
/P.S./	BAUMER P. et al.: "Symptomatic treatment of adult acute diarrhea..., Clinical equivalence of (R)-Acetorphan and ...", Gastroenterology, vol. 116, no. 4, part 2 – April 1999, page A859.	
/P.S./	FARTHING MJ: "Introduction. Enkephalinase inhibition: a rational approach to antisecretory therapy for ...", Alimentary Phar. & Therapeutics, Dec. 1999, vol. 13, suppl 6, - pages 1-2.	
/P.S./	PRIMI MP et al: "Racecadotril demonstrates intestinal antisecretory activity in vivo.", Alimentary Pharm. & Therapeutics, Dec. 1999, vol. 13, suppl 6, pages 3-7.	
/P.S./	TURVIL JL et al: "Effect of granisetron on cholera toxin-induced enteric secretion ...", Lancet 1997 UK, vol. 349, no. 09061, page 1293.	
/P.S./	CUBEDDU LX et al: "Antiemetic activity of ondansetron in acute gastroenteritis", Alimentary Pharm. And Therapeutics, vol. 11, no. 1, 1997, pages 185-191.	
/P.S./	RAMSOOK et al.: "A randomized clinical trial comparing oral ondasetron with placebo in...", Annals of Emergency Medicine, Apr. 2002, vol. 39, no. 4 – pgs. 397-403.	
/P.S./	FARTHING MJG: "Diarrhoea" A significant worldwide problem", Int'l Journal of Antimicrobial Agents, vol. 14, no. 1, Feb. 2000 – pages 65-69.	
/P.S./	BLANDIZZI et al: "Characterization of a novel mechanism accounting for the adverse cholinergic effects of the anticancer drug irinotecan", British HJournal of Pharmacology, vol. 132, no. Jan. 2001 – pages 73-84.	
	LACHAINE et al: "Cost-effectiveness and quality of life evaluation, in the ontext of current practice, of antiemetics used for the control of chemotherapy induced emesis", European Journal of Cancer, Pergamon Press, Oxford, GB, vol. 33, Nov. 1997, pages S6-S7.	
/P.S./	PIZZOLATO JF et al: "The camptothecins", The Lancet, Lancet Ltd., London, GB, vol. 361, no. 9376, June 28, 2003, pages 2235-2242.	

Examiner Signature	/Phyllis Spivack/	Date Considered	11/21/2008
--------------------	-------------------	-----------------	------------

* Examiner: Initial if considered, whether or not citation is in conformance with MPEP §609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.